Streamlining Scientific Instrument Validation

By Mary Jo Egbert, PMP

Introduction

- Mary Jo Egbert, PMP is a graduate of Georgian Court University and was Genetics Research Assistant at Kings College of London, England, United Kingdom.

- She is an independent expert, sort after to validate complex as well as customized engineering equipment and scientific laboratory instrumentation.

Background

- In the FDA regulated large Pharmaceutical environment, one of the challenges has been company structure. Oftentimes, there is no strong centralization to oversee the validation work being performed.

- As NASA is moving in the right direction towards a new centralized site in West Virginia for Software IV&V efforts, they may also want to consider centralization strategies for scientific instrumentation.

Streamlining. . .

- Mary Jo has seen some of the top validation programs in action having consulted at companies such as Johnson & Johnson and Roche.
- She has adopted a “best practices” approach which she has used to streamline her client’s scientific instrument validations.
- Mary Jo saved Johnson & Johnson $41,500. off the bottom line of a $122,000. validation project.

What is Validation?

- Computer System Validation:

  Establishing documented evidence which provides a high degree of assurance that a computerized system will consistently perform according to predetermined specifications and quality attributes.

What does this mean for Scientific Instruments?

- Equipment Validation / Instrument Qualification is performed to demonstrate:
- The system is functioning as the manufacturer intended.
- The system is capable of supporting the routine type of work it will be used for.

Instrument Validation (cont.)

- The system provides for secure data acquisition and storage.
- Basic physical safety guidelines and procedural controls are in place.
- The system will continue to function in this capacity for a reasonable amount of time.

The Validation Package

- Validation Plan
- Requirements (URS, FS, DS)
- Risk Assessment / Mitigation
- Installation Qualification (IQ)
- Operational Qualification (OQ)
- Performance Qualification (PQ)
- Traceability Matrix
- Validation Report
- SOPs and Training records are referenced.

How much do I need?

- FDA Regulations
- Company Policies

- Risk Assessments:
  Functional Risk Assessment
  System Risk Assessment
- Risk Mitigation

How can we expedite this?

- Not by simply buying vendor test scripts:

  The Performance Qualification (PQ), which may also be referred to as a User Acceptance Test Protocol (UATP) is a highly customized document dependent on user requirements specific to your laboratory.

Vendor Test Scripts (cont.)

- Even if the scripts are purchased, labor costs are still incurred for writing the PQ, script execution and QA review.
- Audits have indicated some vendor test scripts simply mirror the functional testing that the vendor already performed in house.
- May result in a conflict of interest. The company that sells the system is now verifying their own system. In essence you are “letting the fox count the chickens in the hen house.”

Classification of Instruments

- Classification of instruments does expedite the validation process.
- Class “A” instruments
- Class “B” instruments
- Class “C” instruments
  GAMP Categories 1-5

Technical Expertise

- Our approach further classifies instruments into categories such as:

- Chromatography
- Light Separations
- Light Scattering

Streamlining

- The benefit to this approach:
- Saves time during script writing for similar hardware and COTS software applications.
- Requirement focused.
- Eliminates double work which may occur across departmental and/or company lines:
  - Instead of each department drafting the materials, a centralized guidance document exists.

Engineering Client Scenario

- “We have all these different vision systems, there’s no consistency.” –Mechanical Engineer
- “I have no clue how the other system works, I still don’t know how we are going to find the time to document this one.” –Engineer
- “Something needs to be done. It’s like the Wild, Wild West out on the floor.” –Quality Engineer

Our Solution

- As part of a centralized, streamlined approach:
- We performed a physical inventory of all vision system and related equipment across the multiple department's on the floor. We found:
  - Instances of the same COTS software
  - Instances of the same hardware

Streamlined !

- Initial estimated project workflow:
  - 33 COTS Applications
  - 10 Hardware Systems
  - 6 Standard Operating Procedures (SOPs)
- Streamlined project workflow:
  - 11 COTS Applications
  - 3 Hardware Systems
  - 2 Standard Operating Procedures (SOPs)

Benefits

- Estimated over 50% savings in labor costs.
- Enhanced program control.
- Identified back up systems.
- Established cross training between departments.
- Sharing of bugs, fixes and lessons learned.

Conclusion

Streamlining is one of the many approaches applied by Mary Jo Egbert while performing scientific instrument validation/equipment qualification. Mary Jo is always happy to meet to further discuss approaches. Please feel free to contact her at (732) 600 1670 or mje350@msn.com.